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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,587	03/21/2002	Tsutomu Okubo	1422-0520P	4925
2292	7590	01/11/2006	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH			KIM, VICKIE Y	
PO BOX 747			ART UNIT	
FALLS CHURCH, VA 22040-0747			PAPER NUMBER	

1618

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/088,587	Applicant(s) OKUBO ET AL.	
	Examiner Vickie Kim	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13, 14, 16 and 17 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 8-11, 13-14 and 17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election acknowledged

1. Applicants' election with traverse the invention group II of claims 8-11, 13, 14, 17 is acknowledged. Applicants traverse the restriction requirement on the grounds that there would be no burden in searching all the inventions. However, this argument is not persuasive, as not all inventions encompassed by the genus would be classified together, or each invention may not be anticipated by others because each invention is patentably distinct to each other as evidenced by numerous patents(see US4634588) .

Furthermore, even if there were unity of classification, the search of the entire genus in the non-patent(a significant part of a thorough examination) would be burdensome. Theanine is amino acid where it has multiple function and involves various bio-mechanisms. For example, US4624588 uses theanine in deodorizing composition. It is also well known in the art that no single drug controls all types of disorders. Thus, each invention is found to be patentably independent and distinct, further burdensome. Therefore, the restriction requirement is maintained, and made FINAL.

Status of Application

1. Acknowledgement is made of amendment filed 11/8/2004. Upon entering the amendment, the claims 12 and 15 are canceled. The claims 1-11 and 13-14 are amended. New claims 16-17 are added.

2. Claims 1-11, 13-14, 16-17 are now pending. The elected claims 8-11, 13, 14, 17 have been examined. All remaining claims not drawn to the elected invention are withdrawn from further consideration as being non-elected. The following rejections are made.

Response to Arguments

3. Applicant's arguments filed 11/8/2004 have been fully considered but they are not persuasive.

112 1st rejection

The amended claims now recite stopping smoking; or preventing to eliminating withdrawal symptoms. However, the specification or any clinical test result fail to show complete stopping enabled. Without guideline or evidential support, the claimed limitation is not considered to be enabling in view of conventional knowledge that is well accepted by ordinary skilled artisan.

Claim Rejections - 35 USC § 112, enablement

The claim 9 is rejected under 35 USC 112, first paragraph, because the specification, while arguably enabling for regulating the desire for smoking or otherwise suppress craving for nicotine, does not reasonably provide enablement for stopping smoking; or prevention or elimination of withdrawal symptoms.

As previously mentioned in previous office action(see 8/6/04), The specification does not enable any person skilled in the art to which it pertains, or with which it is most

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nearly connected, to make/use the invention commensurate in scope with the claim.

Detailed rejection is substantially same as one issued(8/6/04, In re Wands).

As evidenced by fig. 10(10/10), craving for smoking has not been completely subsided. Therefore, the stopping smoking by having theanine administered is not been enabled but is enabling suppressing craving for smoking or reducing smoking.

For the same reason, preventing withdrawal symptoms can not be enabled wherein the administration of theanine is enabling alleviating withdrawal symptoms caused by stopping smoking or moderation of smoking. In addition to that, the craving for smoking or withdrawal symptoms is not only caused by, or associated by high blood concentration of nicotine(biological stress) but also caused by emotional stress and behavior stress(e.g. habits). Thus, complete stopping smoking; or prevention or elimination of withdrawal symptoms is not fully enabled.

103 rejection

a. In response to applicant argument that the rejection is arrived by "picking and choose" because there are other ingredients are involved in invention disclosed in US'724(Blum) patent. However, the argument is not fully persuasive because the scope of instant claims are also drawn to be broad enough where the other ingredients can be included with different labels(e.g. second or third active ingredients having different biological activity) because the instant claims use open transitional phrase such as "comprising". In response to applicant's argument that the references fail to show certain features of applicant's invention,

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it is noted that the features upon which applicant relies (i.e., a composition consisting essentially of theanine) are not recited in the rejected claim(s), whereas the instant claims are drawn to a composition comprising a smoking craving suppressing substance consisting essentially of theanine. It is conventionally known to any skilled artisan that a chemical compound show more than one biological function. Therefore, the limiting the ingredients with labeling rather than differentiating structure of the composition can not be used to obviate the composition taught by the prior art of the record and still encompassed by the teaching of Blum(US'724). The proposed amendment below would obviate 103 rejection.

103 Rejection

Substantially same.

Proposed Examiner's Amendment

4. A proposed examiner's amendment to the record appears below. This examiner's amendment was proposed to applicant on 12/22/05 but not resolved(agreed) in time given. An indication of proposed amendment was requested in a telephone interview with Mr. *** (associate with Mr. Murphy G. Jr) on 12/23/05.
5. The application has been amended as follows:
 - a. Cancel non-elected claims 1-8 and 16.
 - b. In claim 8, line 1, replace [stopping smoking] with -- suppressing craving for smoking-- right after "for" .

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- c. In claim 8, line 3, replace [a composition comprising a smoking craving suppressing substance] with --- a smoking craving suppressing composition -- .
 - c. In claim 9, lines 2-3, delete [preventing,] and [or eliminating] right after "for".
- Alternatively, it is suggested that [stopping, preventing or eliminating] can be replaced with --reducing or decreasing --.

Conclusion

- 6. No claim is allowed.
- 7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579.

The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**VICKIE KIM
PRIMARY EXAMINER**

Vickie Kim
Primary Patent Examiner
January 9, 2006
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